UNITED STATES DISTRICT COURT
NORTHERN DISTRIC

UNITED STATES OF AMERICA *ex rel.* [SEALED],

Plaintiff,

v.

[SEALED],

Defendants.

23-cv-6290
Judge Pallmeyer
Magistrate Judge Finnegan
Direct

FILED UNDER SEAL AND IN CAMERA PURSUANT TO 31 U.S.C. § 3730(b)

DO NOT ENTER ON PACER

RELATORS' COMPLAINT UNDER THE FALSE CLAIMS ACT

UNITED STATES DISTRICT COURT
NORTHERN DISTRI[illegible]

UNITED STATES OF AMERICA *ex rel.* WYNTER RIDDICK AND BRYCE LUND,

Plaintiff,

v.

DAVITA INC.; DAVITA HEALTHCARE PARTNERS, INC.; VILLAGEHEALTH DM, LLC; AND NEPHROLOGY CARE ALLIANCE, LLC,

Defendants.

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Table of Contents

I. SUMMARY OF CASE 1
III. THE PARTIES 4
A. The Government 4
B. Relators 4
C. Defendants 5
IV. THE LAW 6
A. The False Claims Act 6
B. The Anti-Kickback Statute 8
C. DME Suppliers are Prohibited from Telephonic Solicitation 11
V. BACKGROUND 14
A. ESRD and Dialysis 14
B. Medicare Coverage of Dialysis 15
C. Executive Order on Advancing American Kidney Health 19
D. DaVita 20
VI. DAVITA'S FRAUDULENT SCHEMES 20
A. Overview of DaVita's CKCC Program 20
B. DaVita's CKCC Patient Onboarding Process 21
C. DaVita Makes Illicit Solicitation Calls to Steer Medicare Beneficiaries to DaVita Home Dialysis 27
1. DaVita Obtains Contact Information for Medicare Beneficiaries 27
2. DaVita's Care Coordinators Make Unsolicited Telephone Calls to Medicare Beneficiaries 28
3. DaVita 's Financial Motivation to Steer Patients to Home-based Dialysis 35
4. DaVita Steers CKCC Patients to DaVita Home Dialysis 36
D. DaVita Provides Incentive Payments to Physicians to Induce Medicare Referrals 37
1. Overview of DaVita's Clinical Incentive Program 37
2. DaVita Attempts to Recruit Relator's Lund's Practice to the CIP 41
3. DaVita Gains Access to Patient Medical Records Through the CIP 42
4. DaVita's Fraudulent Scheme to Induce Medicare Referrals 44
VII. COUNTS 46

Plaintiff-Relators Wynter Riddick and Dr. Bryce Lund ("Relators"), on behalf of the United States of America, bring this action against defendants DaVita, Inc., DaVita Healthcare Partners, Inc., VillageHealth DM, LLC, and Nephrology Care Alliance, LLC (collectively "DaVita") for violations of the federal False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA") to recover all damages, civil penalties, and all other recoveries provided for under the FCA.

I. SUMMARY OF CASE

1. Chronic kidney disease ("CKD") afflicts an estimated 37 million Americans, while approximately 786,000 Americans suffer from kidney failure, also known as end-stage renal disease ("ESRD"). For these individuals, "[d]ialysis or a kidney transplant is … needed for survival."[1]

2. Most persons with ESRD in the United States qualify for medical coverage through Medicare. As relevant here, Medicare broadly covers dialysis, including both office-based and home-based dialysis. In recent years, Medicare has adopted policies and initiatives to increase the number of beneficiaries who receive home-based dialysis, and conversely, decrease the number of beneficiaries who receive office-based dialysis.

3. Equipment and related supplies furnished to home dialysis patients are provided by Durable Medical Equipment ("DME") suppliers who in return submit claims to Medicare for reimbursement. By statute and regulation, DME suppliers are expressly prohibited from making unsolicited telephone calls to Medicare beneficiaries. In other words, DME suppliers cannot attempt to sell equipment to Medicare beneficiaries through unsolicited phone calls. If they nonetheless do so, Medicare is prohibited from providing any reimbursement, *i.e.* "Medicare

[1] See Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021, available at https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf (last accessed on July 25, 2023).

payment to a DME supplier that submits a claim generated by improper telephone solicitation is prohibited."[2]

4. DaVita is one of the largest providers of dialysis services and related DME in the United States. In direct violation of the non-solicitation requirement, DaVita engages in a nationwide practice of making unsolicited telephone calls to Medicare beneficiaries with the goal of steering beneficiaries to its home-based dialysis services, including the provision of dialysis equipment and related supplies. Specifically, DaVita made and continues to make cold calls to Medicare beneficiaries to persuade them to start treatment with DaVita under the guise of enrolling beneficiaries in one of its regional Comprehensive Kidney Care Contracting ("CKCC") programs. The names and contact details of the beneficiaries are obtained from the electronic medical records of physicians participating in one of DaVita's CKCC programs and/or clinical incentive programs. The beneficiaries are patients with whom DaVita does not have a prior relationship.

5. In violation of the FCA, DaVita knowingly presented or caused to be presented to Medicare false or fraudulent claims for the reimbursement of home dialysis equipment and related supplies knowing that such claims were false, fictitious or fraudulent in that DaVita certified that the subject transactions complied with applicable legal requirements and were not generated pursuant to prohibited telephone solicitations.

6. Compounding its misconduct, DaVita also engages in a nationwide scheme whereby it pays incentives to physicians in exchange for Medicare referrals. Specifically, starting in or around 2022, DaVita established a Clinical Incentive Program ("CIP") through two

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[2] U.S. v. Med-Care Diabetic & Med. Supplies, Inc., 2014 WL 12279512, at *2 (S.D. Fla. Dec. 23, 2014).

subsidiaries – Defendants VillageHealth DM, LLC and Nephrology Care Alliance, LLC – for the ostensible purpose of, *inter alia*, providing disease management and care coordination services to patients who are covered by certain commercial insurance programs. Medicare beneficiaries are not eligible to participate in the CIP. Under its CIP, DaVita pays nephrologists who implement certain care strategies and achieve certain performance-based metrics.

7. As a condition of participating in and receiving payments under the CIP, nephrology practices must provide DaVita with a wide array of sensitive patient information from their electronic medical records database on a quarterly basis, including patients' contact information, diagnoses, and insurance information. DaVita's stated purpose for demanding this information is to ascertain whether the nephrologist has implemented the care strategies and achieved the performance-based metrics required for payment under the CIP. However, the physician practices are required to provide this information for *all* patients, *i.e.* not only patients who actually participate or are eligible to participate in the CIP.

8. In reality, DaVita surreptitiously harvests the patient information to identify Medicare beneficiaries it can solicit for dialysis services. Then, using the contact information it obtains from physician practices, DaVita improperly solicits Medicare beneficiaries by telephone as discussed above. In this way, DaVita utilizes the CIP payments as a kickback to obtain valuable information in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. In addition to breaching the above-described non-solicitation requirement, reimbursement claims arising from these kickbacks independently violate the FCA as a matter of law.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the claims brought on behalf of the United States pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3732(a).

10. The False Claims Act provides that an action under 31 U.S.C. § 3730 may be brought "in any judicial district in which . . . any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." 31 U.S.C. § 3732(a).

11. Defendants transact business in the Northern District of Illinois, and accordingly, this Court has jurisdiction over Defendants, and venue is appropriate in this District.

III. THE PARTIES

A. The Government

12. The United States is a plaintiff to this action on behalf of the Department of Health and Human Services ("HHS"), the Centers for Medicare and Medicaid Services ("CMS"), and federally funded health care programs.

B. Relators

13. The Relators are Wynter Riddick and Dr. Bryce Lund.

14. Relator Wynter Riddick is a resident of Norfolk, Virginia. She holds certifications as a Medical Assistant and as a Phlebotomist.

15. Ms. Riddick worked for DaVita from approximately January 2022 through June 2022, and during this time, her title was Care Coordinator for the DaVita Integrated Kidney Care division. In that role, Ms. Riddick was responsible for, *inter alia*, performing outbound calls to Medicare beneficiaries in the Chesapeake, Virginia area to recruit them for DaVita's Comprehensive Kidney Care Contracting Program. As discussed herein, Ms. Riddick's work at DaVita gave her insight into the false and fraudulent conduct at issue in this lawsuit.

16. Relator Dr. Bryce Lund is a resident of Freemont, Nebraska. He graduated from Hasting College in 1994 and University of Nebraska Medical Center in Omaha in 1999, where he also completed his residency in Internal Medicine. Dr. Lund completed a fellowship in

Nephrology at the University of Iowa Hospital and Clinics in 2007. Dr. Lund is board certified in both Internal Medicine (maintaining his board certification until recently) and Nephrology (in which he remains board certified). In 2007, Dr. Lund established the Nephrology Care, LLC clinic in Fremont, Nebraska where he provides nephrology services to the city of Fremont and surrounding communities. Dr. Lund was approached by DaVita to participate in DaVita's Clinical Incentive Program but declined to participate. Dr. Lund's interactions with DaVita gave him insight into the false and fraudulent conduct at issue in this lawsuit.

17. Relators have standing to bring this action on behalf of the United States pursuant to 31 U.S.C. §3730(b)(l).

18. Relators' complaint is not based on public disclosures of the allegations or transactions discussed herein within the meaning of 31 U.S.C. § 3730(e)(4)(A).

19. Relators are original sources of the information provided herein within the meaning of 31 U.S.C. § 3730(e)(4)(B).

20. Prior to the filing of this action, and prior to any public disclosure within the meaning of 31 U.S.C. § 3730(e)(4)(A), Relators voluntarily disclosed to the United States the information on which the allegations or transactions discussed herein are based.

C. Defendants

21. Defendant DaVita Inc. is a corporation incorporated in Delaware that maintains its principal place of business in Denver, Colorado.

22. Defendant DaVita Healthcare Partners, Inc. is a wholly-owned subsidiary of DaVita, Inc.

23. Defendant VillageHealth DM, LLC is a wholly-owned subsidiary of DaVita HealthCare Partners, Inc.

24. Defendant Nephrology Care Alliance, LLC is a wholly-owned subsidiary of DaVita, Inc.

25. DaVita Inc., DaVita Healthcare Partners, Inc., VillageHealth DM, LLC, and Nephrology Care Alliance, LLC are collectively referred to as "DaVita" unless otherwise specified.

IV. THE LAW

A. The False Claims Act

26. The FCA "was passed in 1863 as a result of investigations of the fraudulent use of government funds during the Civil War." United States v. Neifert-White Co., 390 U.S. 228, 232 (1968).

27. The FCA "establishes a scheme that permits either the Attorney General or a private party to initiate a civil action alleging fraud on the Government," U.S. ex rel. Eisenstein v. City of New York, New York, 556 U.S. 928, 932 (2009) (citations omitted), and "imposes significant penalties on those who defraud the Government." Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 1995 (2016).

28. The FCA provides, *inter alia*, that any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

29. The terms "knowing" and "knowingly" mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the

truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii).

30. Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

31. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Governments behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

32. "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

33. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099, 47103 (1999), the civil monetary penalties under the FCA are $5,500 to $11,000 for violations occurring on or after September 29, 1999 but before November 2, 2015. See 28 C.F.R. § 85.3.

34. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, the civil monetary penalties under the FCA were adjusted to $13,508 to $27,018 for violations occurring on or after November 2, 2015, subject to periodic adjustments. See 28 C.F.R. § 85.5.

B. The Anti-Kickback Statute

35. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), ("AKS") arose out of congressional concern that remuneration provided to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. To protect the integrity of the Medicare and Medicaid programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach.

36. The AKS makes it a criminal offense to "knowingly and willfully" offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services paid for by a Federal health care program. If any purpose of the remuneration is to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program, the AKS is violated, *i.e.*, a lawful purpose will not legitimize a remuneration that also has an unlawful purpose.

37. Specifically, the AKS provides:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1)-(2).

38. "Federal health care program" is defined as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or (2) any State health care program, as defined in section 1320a-7(h) of this title." 42 U.S.C. § 1320a-7b(b)(1).

39. "Federal health care program" includes both Medicare and Medicaid.

40. "Remuneration" is broadly defined to include any transfer of value, including any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b).

41. The AKS covers any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See United States v. Greber, 760 F.2d 68 (3d Cir.).

42. Violation of the AKS subjects the perpetrator to exclusion from participation in federal healthcare programs and civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

43. The Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG") has published safe harbor regulations that define practices that are not subject to prosecution or sanctions under the federal AKS because such practices would unlikely result in fraud or abuse. See 42 C.F.R. § 1001.952. However, only those arrangements that satisfy all of the conditions set forth in the safe harbor are afforded safe harbor protection.

44. Reimbursement claims to federal health care program that are tainted by violations of the AKS are false claims within the meaning of the FCA. 42 U.S.C. § 1320a-7b(g) ("In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.").

45. Suppliers of DME[3] must enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which DME suppliers may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification, in relevant part:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me. … The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the

[3] Durable Medical Equipment (DME) is sometimes referred to as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). For simplicity, Relators refer to DME in this complaint.

Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act)).[4]

C. DME Suppliers are Prohibited from Telephonic Solicitation

46. By statute and regulation, DME suppliers are prohibited from telephonic solicitation.

47. The relevant statute provides:

> A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:
>
> > (i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.
> >
> > (ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.
> >
> > (iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

42 U.S.C. § 1395m(a)(17)(A).

48. In addition, "[i]f a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier." Id. §§ 1395m(a)(17)(B). In other words, "Medicare payment to a DME supplier that submits a claim generated by improper telephone solicitation is prohibited." U.S. v. Med-Care Diabetic & Med. Supplies, Inc., 2014 WL 12279512, at *2 (S.D. Fla. Dec. 23, 2014).

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[4] CMS, Medicare Enrollment Application, Form 855S available at https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms855s.pdf.

49. Moreover, a supplier that engages in a "pattern of contacts" will be prohibited from participation in the Medicare program. 42 U.S.C. § 1395m(a)(17)(C).

50. In October 2000, CMS adopted a corresponding regulation providing that a DME supplier:

> Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:
> (i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.
>
> (ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.
>
> (iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

CMS, *Medicare Program; Additional Supplier Standards,* 65 FR 60366-01, 2000 WL 1501049 (Oct. 11, 2000) (codifying 42 C.F.R. § 424.57(c)(11)).

51. In adopting the regulation, CMS expressly rejected the notion that a DME supplier could avoid the non-solicitation requirement whenever a provider referred a patient. *Id.* at 60372 ("One commenter suggested that we add an exception to this standard. Specifically, the commenter suggested that we permit telephone contact if the supplier receives a referral from a medical professional involved in the patient's care. Response: While this may be reasonable in some situations, we find it problematic in that it may have unintended consequences as a loophole by allowing suppliers to purchase 'referrals; (client lists) from medical professionals.").

52. In March 2003, HHS-OIG issued a Special Fraud Alert because "[n]otwithstanding the clear statutory prohibition, the Office of Inspector General has received credible information that some DME suppliers continue to use independent marketing firms to make unsolicited telephone calls to Medicare beneficiaries to market DME." HHS-OIG,

Telemarketing By Durable Medical Equipment Suppliers (March 2003), available at https://oig.hhs.gov/documents/special-fraud-alerts/870/Telemarketingdme.pdf.

53. This Special Fraud Alert addresses DME suppliers' use of third-party telemarketing firms as an ostensible basis to circumvent the above-described prohibition on solicitation. HHS-OIG explained:

> Section 1834(a)(17) of the Social Security Act prohibits suppliers of durable medical equipment (DME) from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (i) the beneficiary has given written permission to the supplier to make contact by telephone; (ii) the contact is regarding a covered item the supplier has already furnished the beneficiary; or (iii) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months. Section 1834(a)(17)(B) also specifically prohibits payment to a supplier who knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from federal health care programs.
>
> Notwithstanding the clear statutory prohibition, the Office of Inspector General has received credible information that some DME suppliers continue to use independent marketing firms to make unsolicited telephone calls to Medicare beneficiaries to market DME. Suppliers cannot do indirectly that which they are prohibited from doing directly. Except in the three specific circumstances described in the statute, section 1834(a)(17) prohibits unsolicited telemarketing by a DME supplier to Medicare beneficiaries, whether contact with a beneficiary is made by the supplier directly or by another party on the DME supplier's behalf. Moreover, a DME supplier is responsible for verifying that marketing activities performed by third parties with whom the supplier contracts or otherwise does business do not involve prohibited activity and that information purchased from such third parties was neither obtained, nor derived, from prohibited activity. If a claim for payment is submitted for items or services generated by a prohibited solicitation, both the DME supplier and the telemarketer are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim.

Id.

54. In January 2010, the HHS-OIG revised and reissued its 2003 Special Fraud Alert regarding prohibited telemarketing conduct by DME suppliers. See HHS-OIG, Updated Special

Fraud Alert: Telemarketing by Durable Medical Equipment Suppliers (January 2010), available at https://oig.hhs.gov/documents/special-fraud-alerts/868/fraudalert_telemarketing.pdf.

55. In the updated version of the Alert, the HHS-OIG explained that it "has also been made aware of instances when DME suppliers, notwithstanding the clear statutory prohibition, contact Medicare beneficiaries by telephone based solely on treating physicians' preliminary written or verbal orders prescribing DME for the beneficiaries." Id. at 1.

56. HHS-OIG further explained that the "physician's preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary." Id.

57. Moreover, " [i]f a claim for payment is submitted for items or services generated by a prohibited solicitation, both the DME supplier and the telemarketer are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim, as well as criminal and civil penalties for using interstate telephone calls in furtherance of schemes to defraud." Id. at 2.

V. BACKGROUND

A. ESRD and Dialysis

58. End-Stage Renal Disease "occurs when chronic kidney disease — the gradual loss of kidney function — reaches an advanced state."[5]

59. When a person suffers from ESRD, the person's "kidneys are no longer able to work as they should to meet [his or her] body's needs." Id.

60. A patient with ESRD "need[s] dialysis or a kidney transplant to stay alive." Id.

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[5] MAYO CLINIC, End-stage renal disease (Mar. 8, 2018), available at https://www.mayoclinic.org/diseases-conditions/end-stage-renal-disease/symptoms-causes/syc-20354532.

61. As the National Kidney Foundation explains: "Dialysis is a treatment that does some of the things done by healthy kidneys. It is needed when your own kidneys can no longer take care of your body's needs."[6]

62. Healthy kidneys filter out harmful waste and toxin from the body, and dialysis is design to replicate this function for patients with ESRD.

63. There are over 562,000 dialysis patients in the United States.[7]

B. Medicare Coverage of Dialysis

64. Medicare is a federal government healthcare program that provides healthcare benefits to people who are 65 or older, certain younger people with disabilities, and people with ESRD.[8]

65. Thus, while Medicare is typically limited to individuals over 65 or who suffer from certain disabilities, Medicare generally provides coverage for the treatment of ESRD irrespective of age or disability status.

66. When Congress extended Medicare coverage to ESRD patients in 1972, it "marked the first time that individuals were allowed to enroll in Medicare based on a specific medical condition rather than on age."[9]

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[6] See NATIONAL KIDNEY FOUNDATION, Dialysis, available at https://www.kidney.org/atoz/content/dialysisinfo.

[7] See United States Renal Data System (USRDS), 2022Annual Data Report: Atlas of chronic kidney disease and end-stage renal disease in The United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, USA (1996).

[8] See CMS, What's Medicare, available at https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare.

[9] See CONGRESSIONAL RESEARCH SERVICE, Medicare Coverage of End-Stage Renal Disease (ESRD) (Aug. 16, 2018), at 1, available at https://fas.org/sgp/crs/misc/R45290.pdf.

67. ESRD beneficiaries can be covered by traditional Medicare (fee-for-service) under Medicare Parts A, B, and D or under a Medicare Advantage plan (managed care) under Medicare Part C.

68. More specifically, traditional Medicare provides ESRD beneficiaries services on a fee-for-service basis. Traditional Medicare beneficiaries must pay a yearly premium, a yearly deductible, and a co-pay (also known as co-insurance) each time they receive a covered service.

69. Medicare Advantage, formerly known as Medicare+Choice and sometimes known as Part C, is an alternative to traditional Medicare.

70. Under Medicare Advantage, private entities called Medicare Advantage organizations ("MAOs") directly provide coverage to Medicare beneficiaries and in return receive funding from the federal government. See generally 42 U.S.C. § 1395w-21 et seq.; 42 C.F.R. 422.1 et seq.

71. Like the above-described costs associated with traditional Medicare, Medicare Advantage plans typically require the beneficiary to pay a yearly premium, a yearly, deductible, and per-service co-pay.

72. Currently, only a small subset of ESRD patients are eligible to participate in a Medicare Advantage plan. If a person becomes eligible for Medicare solely due to ESRD, they are generally not permitted to enroll in a Medicare Advantage plan and must use traditional Medicare. Current Medicare beneficiaries who develop ESRD are allowed to remain in their Medicare Advantage plan, but, with few exceptions, cannot switch to a Medicare Advantage plan if they were enrolled in traditional Medicare at the time of ESRD onset.

73. In 2016, Congress passed the 21st Century Cures Act which, *inter alia*, largely removed the above-described limitations on ESRD patients participating in Medicare Advantage plans beginning in 2021.[10]

74. Medicare broadly covers treatment service for ESRD. See 42 U.S.C. § 1395rr(a) ("The benefits provided by parts A and B of this subchapter shall include benefits for individuals who have been determined to have end stage renal disease…").

75. This coverage includes broad coverage of dialysis and related services including dialysis performed in hospitals, at outpatient facilities, and at home:[11]

Dialysis services & supplies covered by Medicare

Service or supply	Covered by Medicare Part A	Covered by Medicare Part B
Inpatient dialysis treatments (if you're admitted to a hospital for special care).	✔	
Outpatient dialysis treatments (if you get treatments in a Medicare-approved dialysis facility).		✔
Outpatient doctors' services. See page 35.		✔
Home dialysis training (includes instruction for you and the person helping you with your home dialysis treatments).		✔
Home dialysis equipment and supplies (like the machine, water treatment system, basic recliner, alcohol, wipes, sterile drapes, rubber gloves, and scissors). See pages 33–34.		✔
Certain home support services (may include visits by trained hospital or dialysis facility workers to check on your home dialysis, to help in emergencies when needed, and to check your dialysis equipment and water supply). See page 35.		✔
Most drugs for home and in-facility dialysis. See page 33.		✔
Other services and supplies that are a part of dialysis (like laboratory tests).		✔

[10] CMS, Contract Year 2021 Medicare Advantage and Part D Final Rule (CMS-4190-F1) Fact Sheet (May 22,2020), available at https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-medicare-advantage-and-part-d-final-rule-cms-4190-f1-fact-sheet ("The Cures Act amended the Social Security Act … to allow all Medicare-eligible individuals with ESRD to enroll in MA plans beginning January 1, 2021.").

[11] CMS, Medicare Coverage of Kidney Dialysis & Kidney Transplant Services, at 18, available at https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf.

76. Medicare spends a tremendous amount of money to reimburse providers for the provision of services to treat ESRD.

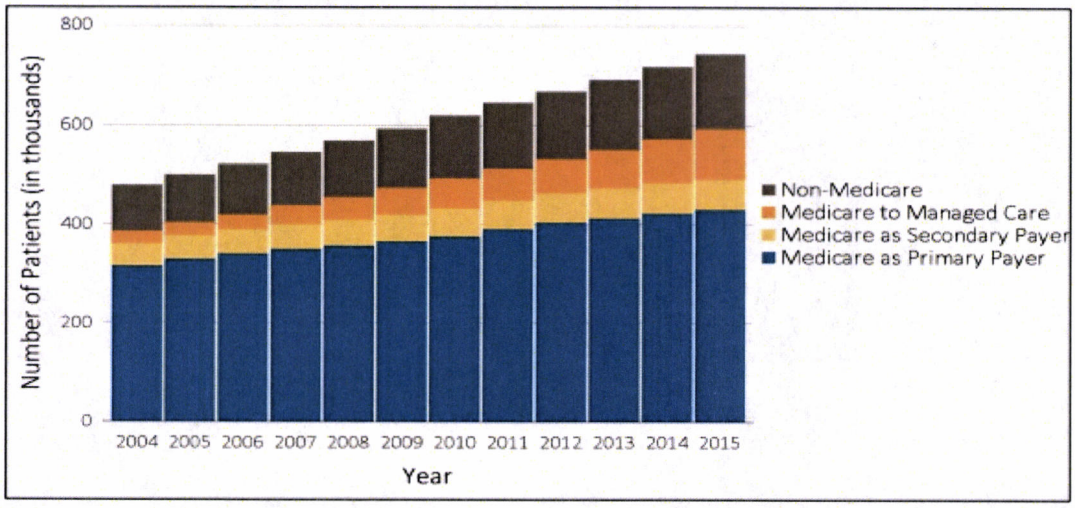
77. For example, in 2015 alone, traditional Medicare spent approximately $34 billion for reimbursement of ESRD treatment services.

78. Medicare spends far more for ESRD Medicare beneficiaries than for non-ESRD Medicare beneficiaries. In one recent year, "Medicare spent $61,996 per ESRD beneficiary, compared to $9,889 per non-ESRD beneficiary."[12]

79. Indeed, "[b]ecause Medicare beneficiaries with ESRD have higher-than-average health care costs, they account for about 7% of Medicare fee-for-service (FFS) spending, while making up about 1% of program enrollment."[13]

80. Medicare provides coverage for the overwhelming majority of ESRD patients in the United States, as compared to other potential providers such as commercial health insurance or Medicaid:[14]

Figure 3. Types of Coverage for Individuals with ESRD in 2015



[12] Supra n. 9, at 8.
[13] Id. at 1.
[14] Id. at 8.

81. Overall, "FFS Medicare covers three-fourths of U.S. annual medical spending to treat ESRD."[15]

C. Executive Order on Advancing American Kidney Health

82. In July 2019, Executive Order No. 13879 on Advancing American Kidney Health ("AAKH") was signed. Exec. Order No. 13879, 84 FR 33817, 2019 WL 3066650 (July 10, 2019).

83. The primary aim of the Executive Order No. 13879 was to increase the utilization of home dialysis and, by the same token, reduce the dominance of in-center hemodialysis in the United States.[16]

84. The AAKH makes it a national goal to increase the adoption of home-based dialysis and kidney transplantation to 80% of the incident ESRD population in the United States by 2025.[17]

85. To achieve this goal, the Centers for Medicare & Medicaid Services' Innovation Center ("CMMI") implemented a mandatory payment model, the End-stage renal disease Treatment Choices model, which adjusts dialysis facilities' and nephrologists' payments based on home dialysis and kidney transplantation rates.

86. CMMI also implemented two voluntary kidney care payment models, Kidney Care First ("KCF") and Comprehensive Kidney Care Contracting, which reward nephrologists

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[15] Id. at 8.
[16] See Exec. Order No. 13879, 84 FR 33817 (July 10, 2019).
[17] Department of Health and Human Services. Advancing American kidney health, available at https://aspe.hhs.gov/sites/default/files/private/pdf/262046/AdvancingAmericanKidneyHealth.pdf (last accessed on June 15, 2023).

and dialysis facilities that successfully reduce the use of in-center hemodialysis through preemptive transplantation or forestalling ESRD.[18]

87. The voluntary payment models explicitly require the inclusion of patients with CKD, with bonuses and penalties attached to slowing CKD progression and transplantation.

D. DaVita

88. DaVita is one of the nation's largest providers of dialysis services and related DME, operating a network of thousands of outpatient dialysis centers across the country, which collectively serve approximately 200,000 patients.

89. DaVita operates its dialysis business through a division called DaVita Kidney Care.

90. DaVita's U.S. dialysis revenues are principally from government-based programs, including Medicare and Medicare Advantage plans, Medicaid and managed Medicaid plans, and other government-based programs.

91. More specifically, over half of DaVita's references is from traditional Medicare and Medicare Advantage plans.

VI. DAVITA'S FRAUDULENT SCHEMES

A. Overview of DaVita's CKCC Program

92. DaVita is an active participant in CMMI's Comprehensive Kidney Care Contracting model.

93. An internal company PowerPoint presentation entitled "CKCC Patient Onboarding: End to End Training – Onboarding Patients to the CKCC Program" contained the following slide:

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[18] CMS, Kidney Care Choices Model: KCF Option, available at innovation.cms.gov/files/x/kcc-kcf-infographic.pdf (last accessed on June 28, 2023).

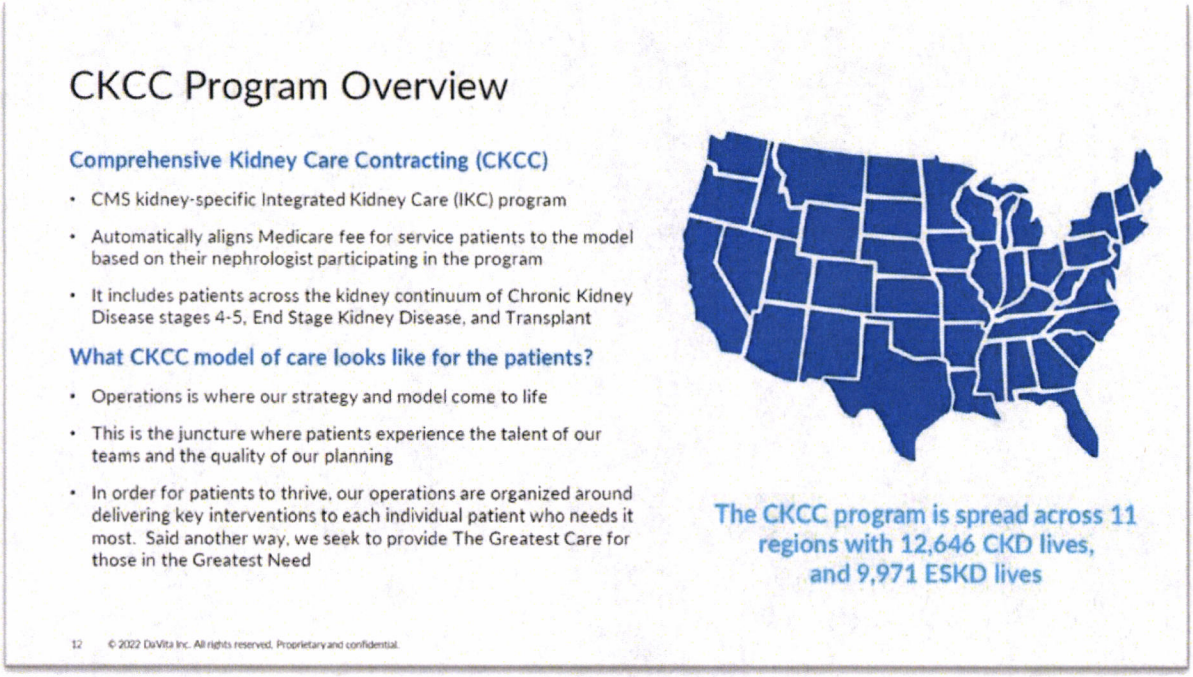


Exhibit 1 at 12.

94. As shown in the above slide, DaVita's CKCC Program is spread across 11 regions in the United States with approximately 12,646 CKD lives and 9,971 ESRD lives.

95. With the launch of its 11 regional CKCC programs, DaVita expected to more than double the number of patients receiving integrated kidney care in the first year alone.[19]

B. DaVita's CKCC Patient Onboarding Process

96. DaVita's CKCC patient onboarding process is described as patient recruitment and solicitation.

[19] See Press Release, DaVita, Kidney Doctors, Transplant Providers Work with DaVita in New Government Program to Help Improve the Lives of Medicare Patients with Kidney Disease (Jan. 19, 2022), available at https://investors.davita.com/2022-01-19-Kidney-Doctors,-Transplant-Providers-Work-with-DaVita-in-New-Government-Program-to-Help-Improve-the-Lives-of-Medicare-Patients-with-Kidney-Disease (last accessed on June 19, 2023).

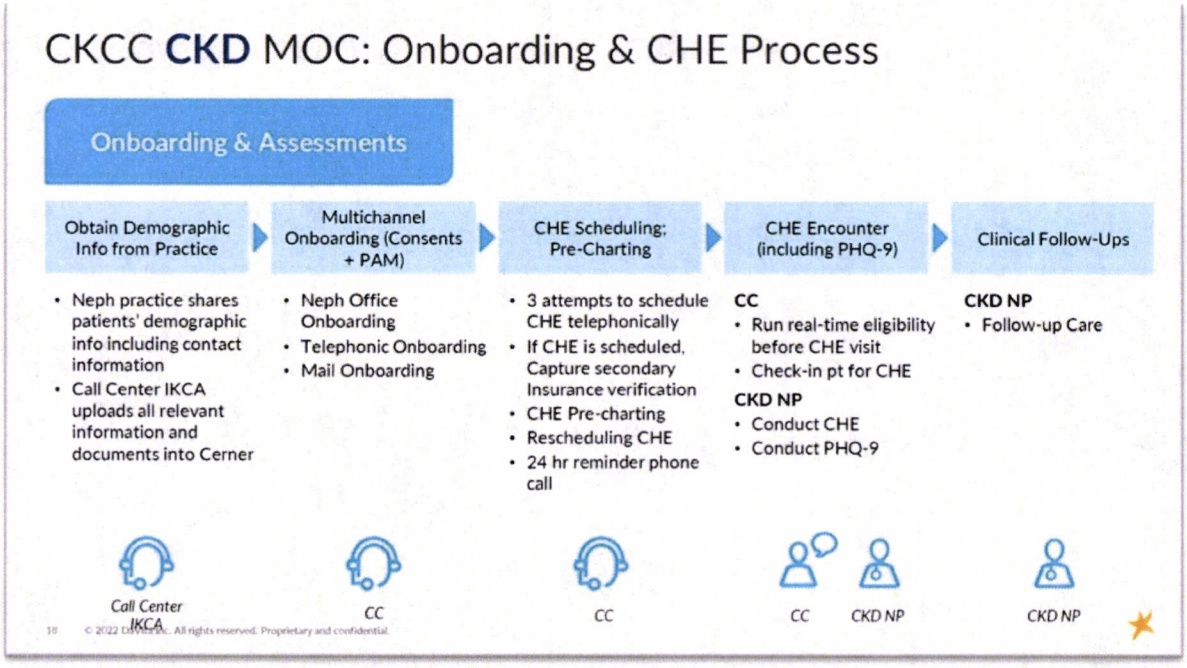
97. Patient recruitment refers to the process of identifying, attracting, screening, and eventually onboarding eligible patients.

98. Recruitment is focused on identifying, attracting, and screening eligible patients, while onboarding is focused on integrating eligible patients into the provider's practice or program.

99. DaVita's actions can be considered patient solicitation because DaVita specifically targets CKD and ESRD patients with whom it has no history of prior contact.

100. DaVita's CKCC patient recruitment process is a critical component in DaVita's fraudulent scheme to solicit Medicare beneficiaries. It is the process by which DaVita identifies potential Medicare beneficiaries to solicit.

101. As illustrated in the following slide from DaVita's CKCC Patient Onboarding Training PowerPoint presentation, the initial and the most critical step in DaVita's CKCC patient recruitment is the identification of patients from the Nephrology Practices' medical records.



102. As discussed in more detail below, nephrology practices that participate in one of DaVita's value-based care programs and/or clinical incentive programs, agree to provide DaVita with patient information from the practices' electronic medical records as one of the conditions to participate in the program and receive incentive payments.

103. This information includes. *inter alia*, the patient names, telephone numbers, insurance provider, and medical diagnosis.

104. DaVita uses the patient information it receives from the practices to create lists of leads, *i.e.* patients who DaVita can recruit and solicit.

105. DaVita's patient onboarding process consists of the following steps: (1) Welcome Patient, (2) Obtain Signed Medical Consents, (3) Obtain Patients PAM Score; and (4) Schedule a Health Evaluation.

106. During the welcome process, patients are introduced to the CKCC Program and its purported benefits.

107. Not all patients proceed beyond the welcome. Some patients for various reasons decline to participate in DaVita's CKCC Program. However, DaVita is not dissuaded by a patient's refusal to participate. DaVita uses multiple strategies through multiple channels to attempt to persuade patients to participate in the CKCC Program, including in-person recruitment during patient doctor's appointment, unsolicited telephone calls, and direct mailing.

108. Patients who agree to participate in DaVita's CKCC Program are asked to sign a series of medical consent forms to, *inter alia*, (1) allow DaVita review and share the patient's electronic records for other providers, (2) allow DaVita to receive the patient's medical records from other providers; and (3) allow DaVita to communicate with the patient through email and

phone call to relay care and other information. Patients are not required to sign the consent form to participate in DaVita' CKCC Program.

109. Patients who agree to participate in DaVita's CKCC Program are asked to complete a Patient Activation Measure ("PAM") questionnaire.

110. Patient activation is defined as understanding one's own role in the care process and having the knowledge, skills, and confidence to take on that role.

111. The PAM is a tool that assesses an individual's skill, confidence, and knowledge for managing one's own health and health care.

112. One challenge for value-based payment models, such as the CKCC Program, is to help patients with high-acuity health challenges and low health literacy become low-acuity, highly health literate populations.[20] The PAM can predict patient behavior such as unwarranted ER visits, hospital admissions, readmissions, care experience, and medication adherence.

113. The PAM is a required CKCC quality measure. For example, as outlined in the following slide from DaVita's CKCC Patient Onboarding PowerPoint presentation, CMS uses the PAMs to assess DaVita's ability to administer two PAMs in 2022 (initial and one follow-up 6 months later).

114. DaVita sought to have all CKCC patients complete the initial PAM as soon as possible because any initial PAMs completed after June 30, 2022 would miss CMS' reporting deadline, as described in the following slide:

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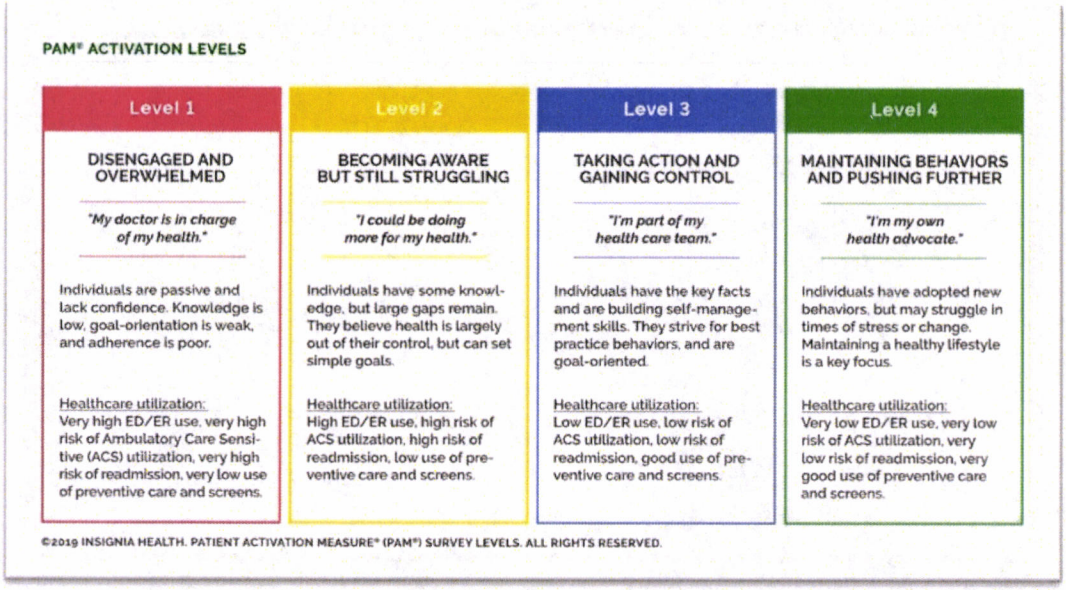
[20] See Alan Snell, The Role Of Remote Care Management In Population Health, Health Affairs Forefront (April 4, 2014), available at https://www.healthaffairs.org/content/forefront/role-remote-care-management-population-health (last accessed on June 19, 2023).

5 The PAM is a Required CKCC Quality Measure

- CMS will measure quality of care in the CKCC, using the PAM to:
  - Assess our ability to administer two PAMs in 2022 (one initial & one follow-up 6 months later)
  - Assess patient improvement on the PAM score
- Who needs an initial PAM? What about the follow-up PAM?
  - All CKCC patients need an initial PAM
  - Timing and administration detail on the follow-up PAM will be available throughout the year
- What is the timeframe for administration of the initial PAM?
  - Complete the initial PAM as soon as possible
  - This provides time to address patient needs before the follow-up PAM
  - Any initial PAM done after 6/30/2022 misses CMS' reporting requirement!

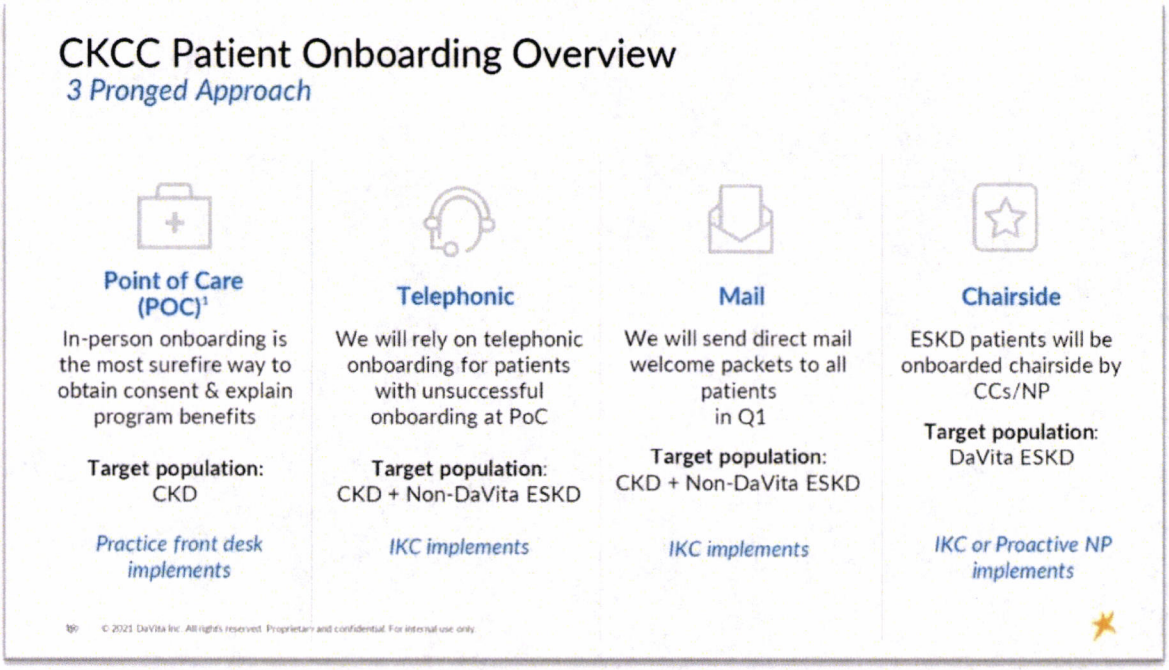
Ex. 1 at 37.

115. As illustrated in the following graphic, PAM Levels 1 and 2 indicate lower patient activation, while PAM Levels 3 and 4 indicate higher patient activation. Typically, patients in PAM Level 4 are proactive with their health and patients in PAM Level 1 likely do not yet understand the importance of their role in managing their own health.



116. For patients who agree to participate in DaVita's CKCC Program, DaVita as part of its onboarding process schedules them for a comprehensive health evaluation ("CHE"), also known as a continuous health evaluation. The CHE is a visit with one of DaVita's nurse practitioners done via video call. The purpose of the CHE is to capture all existing patient comorbidities and document the care management plan.

117. As briefly discussed above, DaVita uses multiple channels to recruit CKCC patients. Patients are recruited in-person at the point of care by nephrology practice staff during their semi-annual nephrologist appointment. For patients who are unsuccessfully recruited at the point of care, DaVita uses a 3-pronged approach to recruit these patients as explained in the following slide from DaVita's CKCC Patient Onboarding PowerPoint presentation:



Ex. 1 at 19.

118. Relevant to this complaint is DaVita's telephonic recruitment process, which is implemented by DaVita IKC Care Coordinators and/or Patient Enrollment Representatives.

119. DaVita's CKCC telephonic recruitment process targets CKD patients and non-DaVita patients with end stage kidney disease ("ESKD").[21] This conduct is prohibited by Section 1834(a)(17) of the Social Security Act because (1) at least one purpose of the recruitment process is to steer patients to DaVita's home-based dialysis services, (2) these patients have not given written permission to DaVita to contact them by telephone and (3) DaVita has no history of furnishing a covered item, such as dialysis equipment, to these patients.

120. Furthermore, Section 1834(a)(17)(B) of the Social Security Act specifically prohibits payment to a DME supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation.

121. Thus, claims for DME equipment such as for home dialysis machines submitted to Medicare for reimbursement resulting from DaVita's telephone solicitation of CKCC program recruits are false claims.

C. DaVita Makes Illicit Solicitation Calls to Steer Medicare Beneficiaries to DaVita Home Dialysis

122. DaVita engages in a nationwide systematic practice of making unsolicited telephone calls to Medicare beneficiaries under the guise of enrolling them in one of its regional CKCC programs.

123. Armed with Medicare beneficiaries' contact and demographic information supplied by partnering nephrology practices, DaVita cold calls Medicare beneficiaries to recruit them to participate in its CKCC Program with the goal of capturing a share of these beneficiaries for its home-based dialysis services.

1. DaVita Obtains Contact Information for Medicare Beneficiaries

[21] End-stage kidney disease ("ESKD") is also known as end-stage renal disease ("ESRD"). The two terms are often used interchangeably.

124. The first step and most critical component in DaVita's fraudulent scheme is to obtain the demographic and contact information for Medicare beneficiaries from its network of partnering nephrology practices.

125. As detailed below, DaVita obtains patient information from nephrology practices that participate in the Clinical Incentive Program. As a condition of participating in the CIP, nephrology practices are required to provide DaVita with a dataset of patient information downloaded from the practices' electronic medical records platform on a quarterly basis. The dataset includes information pertaining to medical diagnoses and care, insurance and payment information, and contact information.

126. DaVita uses its access to these medical records to identify Medicare beneficiaries by data mining the files. Patients not covered by Medicare are not eligible to participate in the CKCC Program, therefore DaVita has no interest in collecting the contact information for non-Medicare covered patients.

127. Ostensibly, the Medicare beneficiaries identified by DaVita's data mining efforts are those with whom DaVita has had no substantial prior contact or established relationship, otherwise there would be no need for DaVita to rely upon the medical records of the Nephrology Practices to obtain the patient contact and demographic information.

2. DaVita's Care Coordinators Make Unsolicited Telephone Calls to Medicare Beneficiaries

128. As part of its fraudulent scheme to solicit Medicare beneficiaries, DaVita created the role of IKC Care Coordinators in or around 2022 in conjunction with the anticipated launch of its 11 regional CKCC programs.

129. Care Coordinators are assigned to one or more of DaVita's regional CKCC program locations. The responsibilities of regional Care Coordinators, as described below, are uniform across the country.

130. Relator Riddick worked as a Care Coordinator for DaVita in the Chesapeake, VA area from approximately January 2022 through June 2022, and in that role, witnesses the below-described misconduct firsthand.

131. At DaVita, Care Coordinators serve as the single point of contact to coordinate resources such as program enrollment (*i.e.*, recruitment/onboarding) and referrals and appointment for DaVita patients.[22]

132. As stated in a job posting for an IKC Care Coordinator position in Newport News, VA, the essential duties and responsibilities of a Care Coordinator include the following: "[(1)] [P]erforms outbound calls and responds to inbound calls from members, providers, and Village resources. … [(2)] Helps identify eligible resources for members and works with Integrated Care Nurses, dialysis clinics, health plans, and other stakeholders to help members enroll in eligible programs. [(3)] Assists with the referral process & coordinates provider appointments on behalf of DaVita IKC members."[23]

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[22]See DaVita Careers: Integrated Kidney Care available at https://careers.davita.com/integrated-kidney-care (last accessed on June 20, 2023).

[23]See DaVita Careers: Integrated Kidney Care available at https://careers.davita.com/job/R0252826/Care-Coordinator-in-NEWPORT-NEWS-VA (last accessed on June 20, 2023).

133. The qualifications for Care Coordinators include: (1) at least 2 years of experience in a professional office environment, (2) a High School Diploma, (3) Patient Care Technician or Administrative Assistant experience in dialysis (preferred), and (4) Medical Experience (preferred).[24]

134. As directly relevant here, Care Coordinators serve as the point of contact for recruiting CKCC patients who are unsuccessfully onboarded during their semi-annual office appointment with their nephrologist.

135. As explained in detail above, one of the primary methods used by DaVita to initiate contact with patients who were not successfully onboarded during their semi-annual nephrologist appointment is to call the patients by telephone. CKD beneficiaries and non-DaVita ERSD beneficiaries are the targets of these telephone calls. In contrast, ERSD beneficiaries receiving dialysis services at a DaVita facility are typically onboarded at chairside while receiving dialysis or visiting a DaVita facility, and are not the subject of this complaint.

136. DaVita provides each Care Coordinator and/or Patient Enrollment Representative with electronic Excel spreadsheets that list the names and contact information of Medicare beneficiaries, including the beneficiaries' telephone numbers and home addresses.

137. These spreadsheets serve as lead lists for recruiting beneficiaries and are created based upon the information mined from the electronic medical records of the nephrology practices that partner with DaVita.

138. The spreadsheets also contain, *inter alia*, the Medicare beneficiaries' date of birth, insurance provider, medical history, and name of treating nephrologist.

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[24] See id.

139. The spreadsheets contain a separate tab that lists the details for "CKD beneficiaries" and a separate tab that lists the details for "non-DaVita ESKD beneficiaries".

140. For the purpose of the spreadsheets and DaVita's CKCC recruitment process, "CKD beneficiaries" refer to Medicare beneficiaries with late stage chronic kidney disease who are not receiving any treatment and/or services at a DaVita treatment facility but are expected to typically start dialysis within 30 to 60 days.

141. "Non-DaVita ESKD beneficiaries" refer to Medicare beneficiaries with end-stage kidney disease who are not receiving dialysis treatment from a DaVita dialysis facility. Non-DaVita ESKD beneficiaries are typically receiving dialysis treatment at either a Veterans Health Administration dialysis facility, Fresenius Medical Care dialysis facility, or a Renal Advantage Inc. dialysis facility. Relator Riddick indicates that DaVita makes a concerted effort to encourage non-DaVita ESKD beneficiaries to receive care at a DaVita facility.

142. Care Coordinators are assigned to specific CKCC regions and are responsible for recruiting Medicare beneficiaries who reside within the geographical region based on the names and contact information provided in the spreadsheets.

143. DaVita provides Care Coordinators with a detailed call script to follow when interacting with Medicare beneficiaries for the purpose of recruiting/onboarding CKCC patients.

144. The call script guides the Care Coordinators through the patient recruitment process and instructs the Care Coordinators on exactly what to say and how to interact with the patients throughout the recruitment process. To gain the confidence of patients, the call script instructs Care Coordinators to tell patients that the CKCC Program has been endorsed by the patient's nephrologist.

145. For example, Care Coordinators typically greet patients at the beginning of the recruitment call by saying "[Dr. (name of treating nephrologist)] wanted me to reach out to you to introduce a new benefit that's now available to you as a Medicare member." This is one ploy that DaVita uses to try to sway and/or manipulate beneficiaries into enrolling in the CKCC Program.

146. The CKCC onboarding call script is provided to Care Coordinators during training and instructs the Care Coordinator to inform beneficiaries at the start of each call that the Care Coordinator is "calling on a recorded line from DaVita Integrated Kidney Care, also known as DaVita IKC."

147. DaVita also provided Care Coordinators with call scripts that directed Care Coordinators not to identify themselves as a DaVita employee.

148. The call script guides Care Coordinators through multiple scenarios on how to deal with patients who may be "very resistant" or "ambivalent" to enrolling in the CKCC Program. In these instances, the call script instructs the Care Coordinators on how to persuade these patients to enroll in the program, which may occur over multiple follow up calls from the Care Coordinator.

149. Care Coordinators are responsible for obtaining the signed medical consent forms and completed PAM questionnaires from patients who decided to participate in the CKCC Program.

150. Relator Riddick was initially responsible for obtaining the consent forms and completed PAMs from patients receiving treatment at a DaVita treatment facility and home-based dialysis patients visiting a DaVita treatment facility.

151. Relator Riddick later was responsible for making outbound calls to non-DaVita patients with CKD to obtain signed consent forms and completed PAMs.

152. Care Coordinators are assessed based upon the number of patient calls completed, the number of signed consent forms obtained, the number of completed PAMs obtained, and the number of CHEs scheduled each day.

153. Care Coordinators are required to update the spreadsheets to reflect the number of times a patient was called and the types of patient interactions, if any that occurred during the call (*i.e.*, obtained signed consent forms, administered PAM, or scheduled CHE).

154. Care Coordinators frequently receive text messages from their regional supervisors asking "How many calls did you make? How many PAMS did you complete? How many consents did you complete? or How many CHEs did you schedule?"

155. DaVita created a real-time "live" version of the spreadsheets which Care Coordinators are required to update after every attempted call to a patient. DaVita Leadership typically monitors these spreadsheeting every 30 – 60 minutes to check whether Care Coordinators are meeting certain call thresholds.[25]

156. DaVita places special emphasis on Care Coordinators obtaining completed PAMs because CMS' measures the quality of care in DaVita's CKCC regional programs using the PAM.

157. According to the knowledge and belief of Relator Riddick, most patients are not competent enough to understand the PAM or simply are not interested in completing the PAM.

[25] At the time Relator Riddick worked as a Care Coordinator in DaVita's Newport News VA office, DaVita Leadership included Maureen Paisley and Eric Gills.

158. For patients who lack the ability to or interest in completing the PAM, Care Coordinators were advised by DaVita Leadership[26] to complete the PAM on behalf of these patients.

159. Care Coordinators were also instructed by DaVita Leadership that if the patient's caregiver or family member answers the phone, it is acceptable for the patient's caregiver or family member to complete the PAM and consent forms on the patient's behalf.

160. Subsequently, DaVita provided Care Coordinators with a caregiver PAM. The caregiver PAM accesses the level of activation in those informal caregivers who play a role in managing the health of the person they care for.

161. Eventually, Care Coordinators were told by DaVita Leadership that it was acceptable for a patient's caregiver or family member to complete the medical consent forms by "signing" the patient's name.

162. At some point Care Coordinators began to raise concerns about patients not answering the telephone or refusing to participate in the recruitment/onboarding process.

163. Subsequently, DaVita instructed Care Coordinators to call patients while the patients are onsite at their nephrologist office for their semi-annual appointments. In some instances, Care Coordinators are permitted to occupy designated rooms onsite at nephrologists' offices and make outbound calls to patients as the patients arrive onsite for a doctor's appointment. In these instances, Care Coordinators were advised not to identify themselves as DaVita employees in order not to "spook" patients not yet receiving dialysis treatment.

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[26] The DaVita Leadership instructions were given by Maureen Paisley and Eric Gills. Leadership instructions from Paisley and Gills would be passed down to Care Coordinators through either Michele Norton RN, Danielle McWhite NP, Caryn McFee Regional Operating Manager for Tidewater area, or Emilia D'aze Regional Operating Manager for Richmond area.

164. At some point, Caryn McFee (DaVita Regional Operating Manager for Tidewater area) notified Care Coordinators and other members of the CKCC team to stop calling non-DaVita patients, in particular Fresenius patients. Fresenius Medical Care sent DaVita a cease and desist letter regarding the solicitation of its patients. Since then, Care Coordinators no longer knowingly recruit Fresenius patients, but continue to recruit non-DaVita patients receiving treatment at Veterans Health Administration facilities or Renal Advantage Inc. facilities.

3. DaVita's Financial Motivation to Steer Patients to Home-based Dialysis

165. CMMI's CKCC model has the stated goal of managing the care of late stage CKD and ESKD patients to delay the progression of kidney disease, promote home dialysis, and incentivize transplants.

166. The stated intent of CMMI's CKCC model is "encourage greater use of home dialysis and kidney transplants for Medicare beneficiaries with ESKD."[27]

167. DaVita's IKC business is an active participant in CMMI's CKCC model.

168. DaVita has invested substantial resources, and expects to continue to invest substantial resources in the CKCC model as part of DaVita's overall plan to grow its integrated kidney care business and value-based care initiatives.

169. Home-based dialysis is dialysis treatment performed at home. There are two types of home dialysis modalities: home hemodialysis ("HHD") and peritoneal dialysis ("PD").

170. Home hemodialysis is similar to in-center dialysis. With home hemodialysis, a small, more portable machine is kept in the patient's home to clean the patient's blood. The patient's blood flows from two needles connected to tubing, usually in the patient's arm, to a machine that removes waste and fluid. The clean blood is then returned to the patient's body.

[27] See CMS, Kidney Care Choices Model, available at https://innovation.cms.gov/files/x/kcc-infographic.pdf (last accessed on June 21, 2023).

171. In home peritoneal dialysis, a cleansing fluid goes into the patient's abdomen through a small tube called a PD access. The fluid stays inside the patient for several hours, removing waste and water from the blood vessels of the peritoneum (lining of your abdomen). The fluid is then drained out and replaced with clean fluid. PD can work by gravity or with a machine.

172. In recent years, DaVita has endeavored to expand its home dialysis business, *i.e.* to shift patients from office-based dialysis to home-based dialysis.

173. Home-based dialysis services, represented approximately 18% of DaVita's dialysis patient services revenues in the United States in 2022.

174. Medicare Part B covers certain home dialysis-related equipment and supplies (like the dialysis machine, water treatment system, basic recliner, alcohol, wipes, sterile drapes, rubber gloves, and scissors).

175. As described above, the overwhelming majority of ESRD patients receive coverage from traditional Medicare for ESRD treatment services, including in-center dialysis, home-based dialysis, kidney transplants, and related services.

176. DaVita submits claims for reimbursement to Medicare for the home-based dialysis related equipment and supplies.

4. DaVita Steers CKCC Patients to DaVita Home Dialysis

177. The July 2019 the Executive Order on Advancing American Kidney Health has paved the way for DaVita to expand its home-based dialysis business.

178. A primary objective of AAKH is to promote home-based dialysis.

179. As discussed above, for patients in the CKCC Program, DaVita and its partnering nephrologist are incentivized to, *inter alia*, steer these patients to home-based dialysis as an alternative to in-center dialysis.

180. Roughly 85% of ESRD patients are eligible for in-home dialysis.[28]

181. Traditionally, only one-third of ESRD patients beginning maintenance dialysis are presented with PD as an option, and only 12% of patients are presented with HHD as an option.

182. Patients are prescribed home-based therapy by a nephrologist, who is typically contracted to work exclusively with one of the large dialysis chains, such as DaVita.

183. DaVita's relationships with its network of prescribing nephrologists – including through the Clinical Incentive Program detailed below – serves as a key component in DaVita's ability to steer Medicare beneficiaries to home-based dialysis.

D. DaVita Provides Incentive Payments to Physicians to Induce Medicare Referrals

184. Compounding its misconduct, DaVita also engages in a nationwide scheme whereby it provides incentive payments to physicians in exchange for Medicare referrals.

185. Specially, DaVita engages in a scheme whereby it offers incentive payments to physicians through its Clinical Incentive Program to gain access to their patient medical records to, *inter alia*, identify Medicare referrals who DaVita then solicits for Medicare reimbursed healthcare services.

1. Overview of DaVita's Clinical Incentive Program

186. In or around 2022, DaVita created the CIP through its subsidiary Nephrology Care Alliance

187. DaVita promotes the CIP as a clinical, outcomes-based payment program designed to improve patient outcomes and lower total patient cost in partnership with nephrologists.

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[28]See Rivara MB, Mehrotra R. The changing landscape of home dialysis in the United States. Curr Opin Nephrol Hypertens. 2014 Nov;23(6):586-91, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4414038/#R9 (last accessed on Aug. 25, 2023).

188. The CIP is offered to nephrologists for program-eligible patients through DaVita's Integrated Kidney partnership with commercial payors.

189. Participating nephrologists are incentivized based on achievement of certain clinical metrics for their program-eligible patients.

190. An overview of the CIP is provided in the following slide that was included in a PowerPoint presentation entitled "Clinical Incentive Program: Overview and Guide".

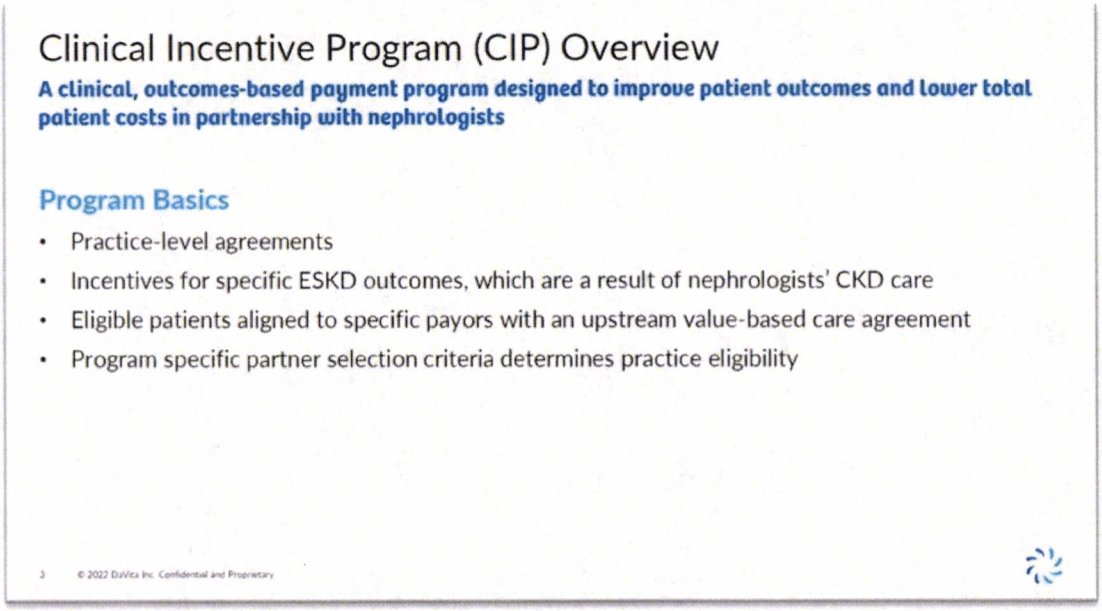


Exhibit 2 at 3.

191. To participate in the CIP, Nephrology Practices must, *inter alia*, enter into a Clinical Incentive Program Agreement ("CIP Agreement" or "Agreement").

192. As described below, Relator Dr. Lund directly received a template of the CIP Agreement when DaVita attempted to recruit his practice to participate in the CIP. **Exhibit 3**.

193. The CIP Agreement is a practice level agreement. Id. at 1.

194. The CIP Agreement is made and entered into by and between VillageHealth DM, LLC for itself and on behalf of Nephrology Care Alliance, LLC (collectively "Company") and

the participating practice. Id. at 1.

195. The CIP Agreement is for three years unless terminated earlier by mutual agreement. Id. at 6 § 15.

196. Practice is defined as "a contracted provider with one or more of the Programs and is qualified to provide professional medical services to Program members with CKD and ESRD." Id. at 1 § B.

197. Members are defined as "the Practice's patients who are qualified under certain commercial plans … through the patient's disease state or medical diagnosis." Id.

198. DaVita through VillageHealth DM, LLC and Nephrology Care Alliance contracts with certain commercial programs ("Programs") for the purposes of, *inter alia*, proving disease management and care coordination services to patients with CKD and ESRD who are covered under such Programs.

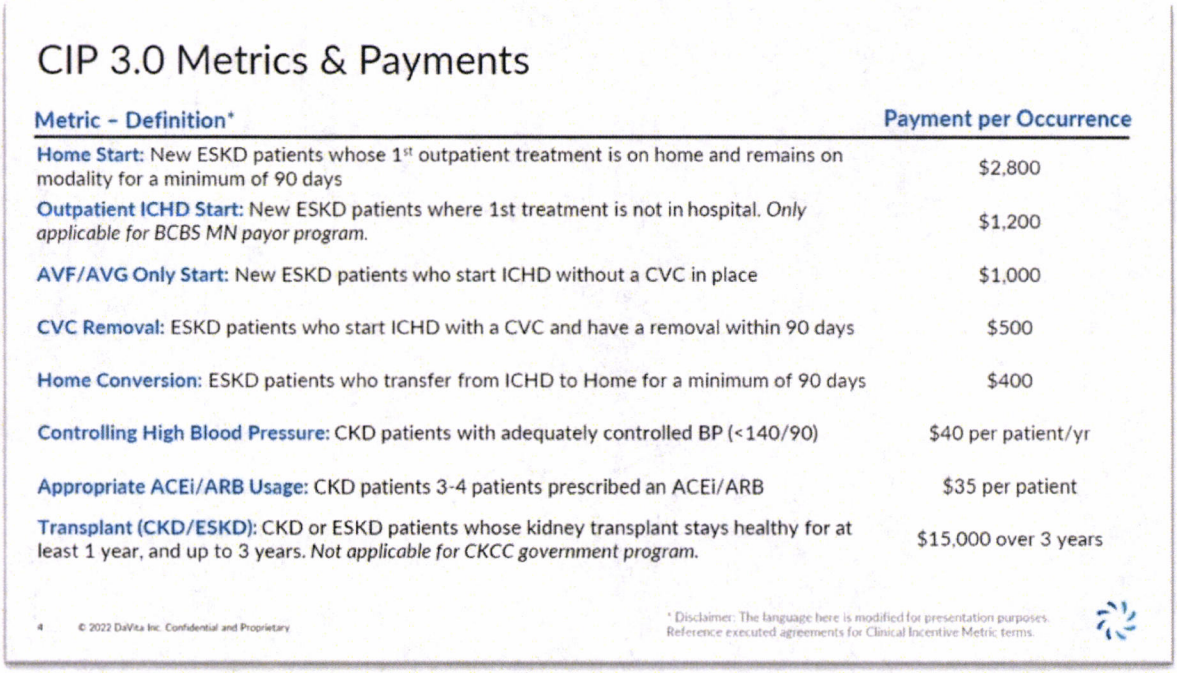
199. From time to time, DaVita modifies the list of Programs. As of April 2022, commercial payers participating in the CIP included: Cigna Health Corporation; Humana Insurance Company, United Healthcare Insurance Company, Aetna Network Services, LLC, UCare Minnesota, and Blue Cross and Blue Shield of Minnesota.

200. Practices ("Participating Physicians") participate in the CIP through their nephrologists.

201. In order to participate in the CIP, Participating Physicians must, *inter alia*, sign a joinder to the CIP Agreement where the Participating Physician agrees to abide by the terms and conditions of the CIP Agreement.

202. Under the CIP Agreement, DaVita agrees to make payments to providers based on implementation of certain patient care strategies and achieving certain clinical metrics ("Metrics").

203. For illustrative purposes, see the following slide Nephrology Care Alliance included in a PowerPoint presentation entitled "Clinical Incentive Program: Overview and Guide":



CIP 3.0 Metrics & Payments

Metric – Definition*	Payment per Occurrence
Home Start: New ESKD patients whose 1st outpatient treatment is on home and remains on modality for a minimum of 90 days	$2,800
Outpatient ICHD Start: New ESKD patients where 1st treatment is not in hospital. *Only applicable for BCBS MN payor program.*	$1,200
AVF/AVG Only Start: New ESKD patients who start ICHD without a CVC in place	$1,000
CVC Removal: ESKD patients who start ICHD with a CVC and have a removal within 90 days	$500
Home Conversion: ESKD patients who transfer from ICHD to Home for a minimum of 90 days	$400
Controlling High Blood Pressure: CKD patients with adequately controlled BP (<140/90)	$40 per patient/yr
Appropriate ACEi/ARB Usage: CKD patients 3-4 patients prescribed an ACEi/ARB	$35 per patient
Transplant (CKD/ESKD): CKD or ESKD patients whose kidney transplant stays healthy for at least 1 year, and up to 3 years. *Not applicable for CKCC government program.*	$15,000 over 3 years

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* Disclaimer: The language here is modified for presentation purposes. Reference executed agreements for Clinical Incentive Metric terms.

Ex. 2 at 4.

204. Exhibit A of the CIP Agreement provides a detailed outline of the CIP Payment Methodology. *See* Ex. 3-A.

205. Under the CIP Agreement, Payment is conditioned on, in relevant parts:

> "[(a)] Practice shall prepare and maintain records of all services provided to Members, complete and submit accurate claims, and deliver to [DaVita] upon [DaVita]'s request such information as is necessary for [DaVita] to determine that the services have been performed and the Metrics have been met, each in a form satisfactory to [DaVita]. … [(c)] **Practice shall permit [DaVita] to perform a pre-payment audit of Program**

> **Participants' medical records pertaining to the Members, Member claims, and other records as necessary for [DaVita] to determine if the services have been performed and the Metrics have been met.** If required, Practice shall provide evidence satisfactory to [DaVita], in its reasonable discretion, proving resolution of matters identified during such pre-payment audit [emphasis added]."

Ex. 3 § 5(a)-(c).

2. DaVita Attempts to Recruit Relator Dr. Lund's Practice to the CIP

206. DaVita repeatedly attempted to recruit Relator Dr. Lund's practice to participate in the CIP.

207. Relator Dr. Lund first heard about the CIP in March 2021 when he was contacted (unprompted) by Tate Rich, whose title at the time was Senior Director of Business Development at DaVita.

208. On or about March 18, 2021, Relator Dr. Lund spoke on the phone with Mr. Rich about the CIP.

209. Following the phone call, Mr. Rich emailed Relator Dr. Lund a document describing the CIP and the above-described CIP Agreement. **Exhibit 4.**

210. After this initial discussion DaVita repeatedly contacted – typically every two to three months – Relator Dr. Lund in a protracted effort to persuade him to participate in the CIP.

211. Mr. Rich also emailed Relator Dr. Lund in April 2021 to ask whether he was interested in participating in the CIP.

212. Relator Dr. Lund's understanding is that Mr. Rich left DaVita at some point in 2021, at which point DaVita's recruitment efforts transitioned to Michael Pixton whose title is also Senior Director of Business Development.

213. In mid-2022, Relator Dr. Lund spoke with Mr. Pixton by Zoom/telephone to discuss the possibility of Relator Dr. Lund's practice participating in the CIP.

214. Among the items that Mr. Pixton and Relator Dr. Lund discussed was the

process, described further below, by which DaVita accesses patient information from the electronic medical records of practices that participate in the CIP for the purported purpose of tracking performance-based metrics.

215. Relator Dr. Lund never enrolled his practice in the CIP; however, through DaVita's extensive recruitment efforts, he gained firsthand insight into the operation of the CIP.

3. DaVita Gains Access to Patients' Contact and Medical Information

216. DaVita receives an array of patient data from the electronic medical records ("EMR") platforms of providers that participate in the CIP.

217. As a condition of payment under the CIP, each practice agrees to provide DaVita with patient information for the ostensible purpose of, *inter alia*, auditing such information to determine if the services have been performed and the performance metrics have been met.

218. DaVita obtains the patient information from practices participating in the CIP on a quarterly basis.

219. In most instances, the information is exported from a practice' EMR platform in a CSV (comma-separated values) file and then uploaded to DaVita's database.

220. A CSV file is a text file that has a specific format which allows data to be saved in a structured format and easily transferred from one database to another database.

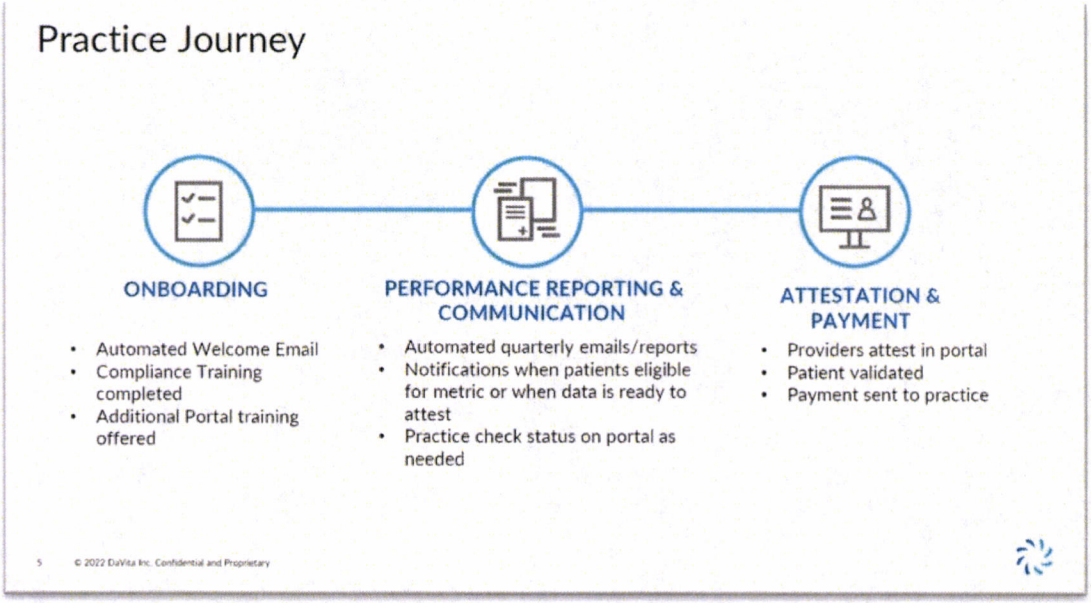
221. Most EMR platforms have the functionality to export data in CSV format.

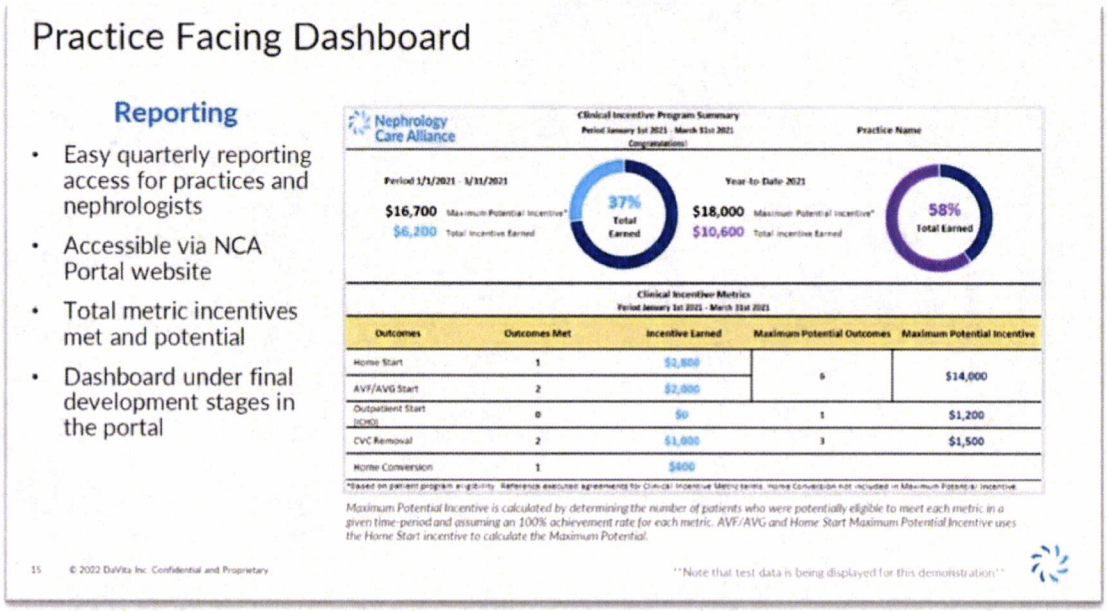
222. DaVita's IT team works with each practice to accomplish the transfer of patient information.

223. The information includes the names and contact details of all patients at the practice, as well as, *inter alia*, their date of birth, medial history, diagnostic results, and insurance provider. This is a "raw" data download of the practice's electronic medical records. The raw data download contains the medical records for patients covered by commercial insurance

providers, as well as patients who are covered by Medicare.

224. The following slides prepared by Nephrology Care Alliance were included in a PowerPoint presentation entitled "Clinical Incentive Program: Overview and Guide" illustrate the process by which Participating Physician participate in the CIP from onboarding to payment:





Ex. 2 at 5, 15.

225. Using the information it receives, DaVita identifies patients who are eligible to participate in the CIP.

226. DaVita pays incentives to CIP Participating Physicians who implement certain patient care strategies and achieve the performance-based metrics developed by DaVita.

4. DaVita's Fraudulent Scheme to Induce Medicare Referrals

227. DaVita enters into CIP Agreements with nephrology practices as described above, for the purpose of, *inter alia*, gaining access to patients' electronic medical records and contact information.

228. The data is then used by DaVita to solicit the practices' patients by phone for Medicare-reimbursed healthcare services.

229. DaVita began entering into CIP Agreements with nephrology practices across the United States in or around January 2022.

230. Pursuant to the CIP Agreements, DaVita pays Participating Physicians a payment for, *inter alia*, implementing certain patient care strategies and achieving certain performance-based metrics. DaVita makes these payments to eligible Participating Physicians on a quarterly basis.

231. However, an additional unwritten purpose of the CIP Agreements is for a practices to provide DaVita with access to their electronic medical records so DaVita can perform data mining and solicit the practice's patients by phone for reimbursable Medicare health care services, neither of which is explicitly mentioned in the CIP Agreements.

232. Once DaVita obtains the data, it surreptitiously performs data mining of the medical records under the guise of the CIP.

233. The CIP Agreement gives DaVita access to secure patient information under the veneer of DaVita conducting "pre-payment audits," but the true intent of the access is for DaVita to mine the medical records for Medicare referrals.

234. The CIP payments are intended at least in part to secure access to patient information in the Practices' electronic medical records. The Nephrology Practices through their Participating Physicians are financially incentivized quarterly in conjunction with the CIP required quarterly download of the Practices' medical records.

235. The definition of "referral" for the purpose of the AKS is broad, encapsulating both direct and indirect means of connecting patient with provider; it goes beyond explicit recommendations to include more subtle arrangements, and inquiry is practical one that focuses on substance, not form. See United States v. Patel, 778 F.3d 607 (7th Cir. 2015)

236. Giving DaVita access to patient information that is used to solicit those patients constitutes a referral under the federal Anti-Kickback Statute 42 U.S.C. § 1320a-7b, albeit an indirect one. See Stop Illinois Health Care Fraud, LLC v. Sayeed, 2021 WL 2331338 (N.D. Ill. June 8, 2021) (if the fees were even partially intended as remuneration for referrals, defendants would be liable under the Anti-Kickback Statute).

237. Since the ultimate effect of the CIP Agreements is for DaVita to gather new Medicare eligible patient contacts, the practices' provision of patient information constitutes a referral.

238. At minimum, DaVita is liable under the AKS on a "file access theory" of referral.

239. Under the "file access theory" of referral, DaVita has violated the AKS, which makes it a crime to knowingly and willfully pay any remuneration in exchange for referrals of items or services reimbursable under a federal healthcare program.

VII. COUNTS

COUNT I
Violation of the False Claims Act - 31 U.S.C. §3729(a)(1)(A)

240. Relators repeat and re-allege each and every allegation contained in the paragraphs above as though fully set forth herein.

241. In violation of 31 U.S.C. § 3729(a)(1)(A), DaVita knowingly presented or caused the presentment of false or fraudulent claims for payment or approval to (1) officials of the United States and/or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

242. The false statements made by DaVita had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims.

243. DaVita made fraudulent and false statements with actual knowledge of the falsity of its statements, with deliberate ignorance of the falsity of its statements, or with reckless disregard as to the falsity of its statements.

244. The government, unaware of the falsity of the records, statements, and claims made or caused to be made by DaVita, has paid and continues to pay DaVita for claims that are tainted by remuneration relationships that violate the AKS, reimbursement to which DaVita is not entitled.

245. By virtue of the false or fraudulent claims that DaVita presented or caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II
False Claims Act – Violation of 31 U.S.C. §3729(a)(1)(B)

246. Relators repeat and re-allege each and every allegation contained in the paragraphs above as though fully set forth herein.

247. In violation of 31 U.S.C. § 3729(a)(1)(B), DaVita knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to (1) the United States or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

248. The false records and statements made by DaVita had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims. By virtue of the false records and statements made by DaVita, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, Relators, on behalf of the United States, demand that judgment be entered in their favor and against Defendants for:

(1) Three times the amount of damages to the United States;

(2) Civil penalties of (a) $5,500-$11,000 for each violation of the FCA that occurred after September 29, 1999 but before November 2, 2015 and (b) $13,508 to $27,018 for each violation of the FCA that occurred on or after November 2, 2015, or within the ranges that exist on the date such penalties are assessed;

(3) Any other recoveries or relief provided for under the FCA;

(4) Relators' receipt of the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs, based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action; and

(5) Such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Relators hereby demand a trial by jury.

Dated: August 28, 2023

/s/ Michael I. Behn

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WALDEN MACHT & HARAN LLP
Daniel R. Miller (*pro hac vice* forthcoming)
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Telephone: (212) 335-2030
dmiller@wmhlaw.com
jdesantis@wmhlaw.com

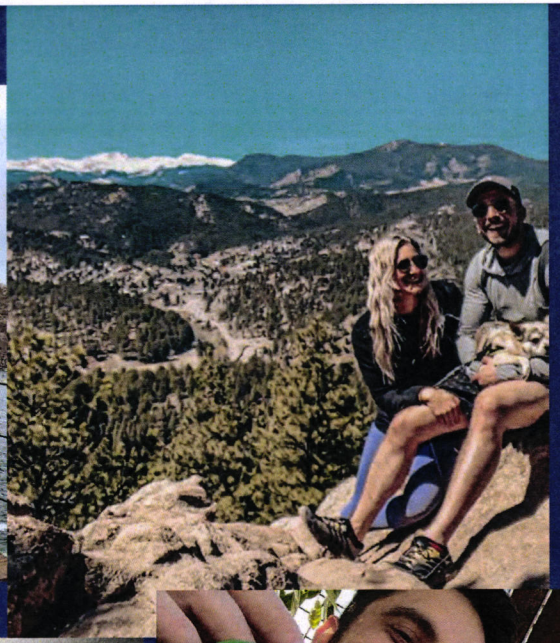
Exhibit 1

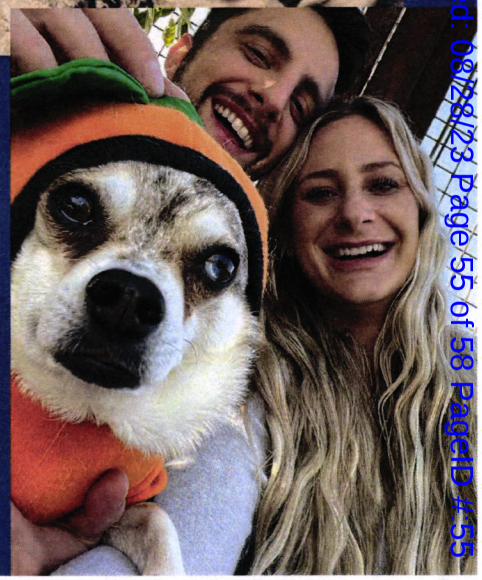
CKCC Patient Onboarding

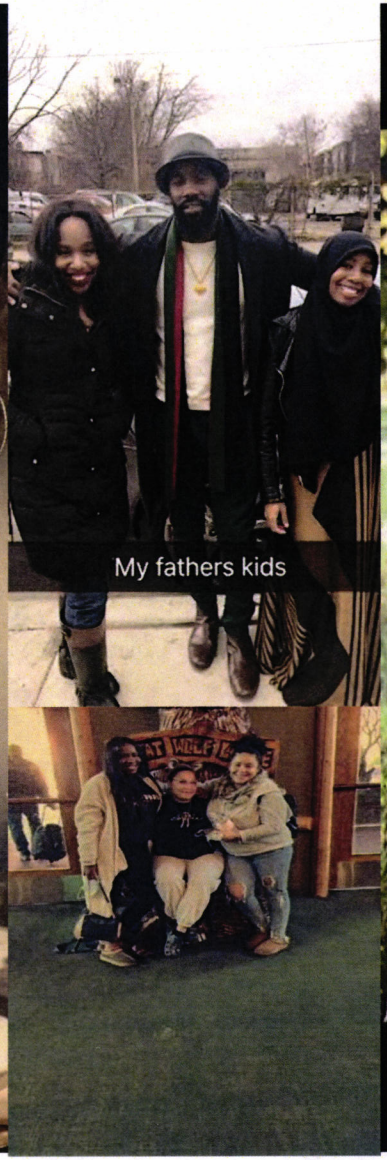
End To End Training – Onboarding Patients To The CKCC Program

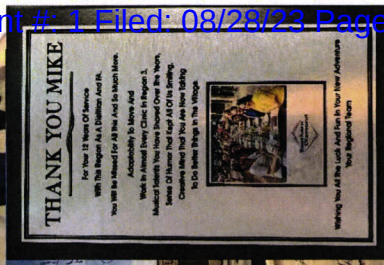
DaVita

Welcome/Introductions





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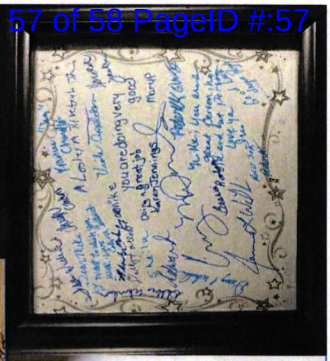

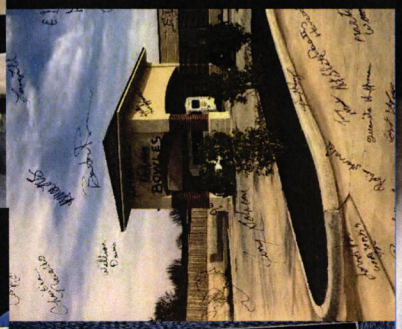


ADVENTURE AWAITS

Welcome, Care Coordinators!!

Cora
Ceddricka
Jennifer
Lathesia
Karla

Evelyn
Tanesha
Chelethia
Joel
Ashley

Martina
Rowena
Amado
Erlene
Shana

Welcome, Call Center IKCA!

Carmen

DaVita

Carissa